

III. REMARKS/ARGUMENTS

A. Status of the Application

Claims 1, 13 and 19 are amended. Claim 39 has been added. Claims 2-7, 18 and 20-27 are cancelled. Claims 28-38 have been withdrawn from consideration.

Claims 1, 8-17, 19 and 39 are under examination in this application. Favorable consideration of claims 1, 8-17, 19 and 39 in light of the following remarks is respectfully requested.

B. Objection to the Specification

Paragraph [0058] of the present application has been amended to refer to the incorporation by reference of U.S. Patent No. 6,929,807 rather than International Patent Application Publication Number WO 98/06418. International Patent Application Publication No. WO 98/06418 corresponds to International Application No. PCT/US97/13379 filed August 4, 1997. U.S. Patent No. 6,929,807 was issued on August 16, 2005 from U.S. Patent Application No. 09/242,215 filed August 4, 1997, which claims priority to International Application No. PCT/US97/13379. The information incorporated into each of the applications is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed, as such, the amendment to the specification does not introduce any no new matter into the present specification.

It is respectfully submitted that the foregoing amendment to the specification of the present application overcomes the objection to the specification. Specifically, the incorporation by reference statement in paragraph [0058] of the present application now refers to a published U.S. Patent.

C. Amendments to the Claims

The amendments to claims 1, 13 and 19 are fully supported by the specification as originally filed. Specifically, claim 1 as amended states:

A dietary supplement composition for a mammal, comprising a nutritionally effective amount of β -glucan, colostrum, lactoferrin, citrus pectin and a nutritionally effective amount of six or more essential saccharides.

In the previous version of claim 1, the phrase “nutritionally effective amount of” was used to modify each term listed thereafter including β -glucan, colostrum, lactoferrin, citrus pectin and six or more essential saccharides. Therefore, the claim could have been rewritten as comprising:

“[A] nutritionally effective amount of β -glucan, a nutritionally effective amount of colostrum, a nutritionally effective amount of lactoferrin, a nutritionally effective amount of citrus pectin and a nutritionally effective amount of six or more essential saccharides”.

However, the Applicants have amended claim 1 to particularly and explicitly point out that the composition includes a nutritionally effective amount of six or more essential saccharides.

Claim 13 is amended to delete mention of citric acid in the claimed composition.

Claim 19 depends from claim 1 and is amended to be consistent with amended claim 1.

New claim 39 is fully supported by the specification as originally filed, specifically paragraph [0076] as well as original claims 1 and 9.

As such, the amendments to claims 1, 13 and 19 as well as new claim 39 are fully supported by the specification as filed and no new matter has been introduced by the amendments.

D. Rejection of Claims 1, 8-17 and 19 under 35 U.S.C. §112, first paragraph

Claims 1, 8-17 and 19 stand rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Applicants assert that claims 1, 8-17 and 19 are fully supported by the specification and no new matter has been introduced. Support for the language “six or more essential saccharides” is found in the specification as amended based on the incorporation by reference of U.S. Patent No. 6,929,807 which corresponds to International Publication No. 98/06418.

For the foregoing reasons, it is requested that the rejection of claims 1, 8-17 and 19 under 35 U.S.C. §112, first paragraph be withdrawn.

E. Rejection of Claims 13 and 19 under 35 U.S.C. §112, second paragraph

Claims 13 and 19 stand rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite. Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Applicants assert that claims 13 and 19 as amended fully comply with 35 U.S.C. § 112, second paragraph and, therefore, respectfully request withdrawal of this rejection.

F. Rejection of Claims 1, 8-17 and 19 under 35 U.S.C. § 103(a)

Claims 1, 8-17 and 19 stand rejected under 35 U.S.C. § 103(a) over the combination of U.S. Patent No. 5,576,015 to Donzis (hereafter referred to as “Donzis ‘015”), U.S. Patent No. 5,531,989 to Paul (hereafter referred to as “Paul ‘989”) and International Patent Application Publication No. WO 97/05884 to Plaut (hereafter referred to as “Plaut ‘884”). Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Applicants submit that the combination of Donzis, Paul and Plaut fails to teach each and every limitation of the amended claims, specifically a composition that includes six or more essential saccharides in a nutritionally effective amount. Therefore, it is requested that the rejection of claims 1, 8-17 and 19 under 35 U.S.C. § 103(a) over the combination of Donzis ‘015, Paul ‘989 and Plaut ‘884, be withdrawn.

Applicants submit that Donzis ‘015, Paul ‘989 and Plaut ‘884 do not teach each and every limitation of the claims as amended. Specifically, the combination of cited references does not teach a composition that includes six or more essential saccharides and even if it did the combination does not teach a composition that includes a nutritionally effective amount of six or more of such essential saccharides.

Applicants strongly disagree with the characterization of guar gum in the Office Action. The Office Action states that:

“guar gum in the prior art would contain six or more essential saccharides as claimed by applicant.”

Applicants do not agree with this characterization and do not concede that guar gum contains six or more essential saccharides. Those of ordinary skill in the art understand and recognize that guar gum is a disaccharide of mannose and galactose in a 1:2 molar ratio. Moreover, even if guar gum did contain six or more essential saccharides, the concentrations of each of the six or

more essential saccharides would not be in a nutritionally effective amount. The Office Action simply makes the statement that guar gum in the prior art would contain six or more essential saccharides; but does not provide any factual support for the statement using evidence.

The United States Patent and Trademark Office is an agency of the U.S. Federal Government and it is particularly important that such an agency's decision on issues of fact be limited to the written record made before the agency. See *Sangamon Valley Television Corp. v. United States*, 269 F.2d 221, 224 (D.C. Cir. 1959). In addition, the Supreme Court rejected an agency's attempt to rely on its own expertise in a contested proceeding in *Baltimore & Ohio R.R. Co. v. Aberdeen & Rockfish R.R. Co.*, 393 U.S. 87, 91-92 (1968). The Supreme Court held that the ICC's decision was not supported by record evidence, and that in such a context agency expertise cannot substitute for record evidence because:

“[t]he requirement for administrative decisions based on substantial evidence and reasoned findings—which alone make effective judicial review possible—would become lost in the haze of so-called expertise.” *Id.* 92.

Applicants assert that the cited references do not factually support, using evidence, each and every limitation of the rejected claims and, therefore, a prima facie case of obviousness has not been established. In this regard, see MPEP § 2143, which states that “[t]o establish a prima facie case of obviousness... the prior art reference (or references when combined) must teach or suggest all the claim limitations.” The Examiner is therefore respectfully requested to furnish support for the assertion that guar gum in the prior art would contain six or more essential saccharides. Furthermore, under MPEP § 2142, “[i]f the examiner does not produce a prima facie case, the Applicants are under no obligation to submit evidence of nonobviousness.”

Accordingly, a prima facie case of obviousness has not been established because each and every limitation of claims 1, 8-17 and 19 is not taught by the combination of Donzis '015, Paul '989 and Plaut '884. Specifically, the combination of cited references does not teach a composition that includes six or more essential saccharides and even if it did the combination does not teach a composition that includes a nutritionally effective amount of six or more of such essential saccharides. As such, the Examiner is requested to provide evidence on the record that the cited references include each and every limitation of the claims as amended including six or more essential saccharides **and** a nutritionally effective amount of each of the six or more essential saccharides or withdraw the rejection.

G. New claim 39

New claim 39 has been added to more particularly point out and distinctly claim one embodiment of the present invention.

H. CONCLUSION

In light of the foregoing, Applicant submits that claims 1, 8-17, 19 and 39 are in condition for allowance, and an early Notice of Allowance of all pending claims is respectfully solicited. The Examiner is invited to call the undersigned at the below-listed telephone number if a telephone conference would expedite or aid the prosecution and examination of this application.

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Respectfully submitted,

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